REMARKS

FORMAL MATTERS:

Claims 1-7, 9-25, 27-34, 36, 37 and 55 are pending in this application.

In this amendment the withdrawn claims 8, 35, and 38-41 are canceled without prejudice to the refilling of these claims at a later time.

No claims are amended here.

SUMMARY

Claim 20 is the only pending independent claim and it has been rejected as not meeting enablement requirements under 35 U.S.C. §112, first paragraph and not being novel under 35 U.S.C. §102.

The enablement rejection focuses on whether the device has been shown to be constructed and arranged so that it establishes a quasi-steady gas flow that is substantially free of shockwaves in the duct system upstream of the primary shockwave. This is obtained by the embodiment shown in Figure 5 and variations thereof shown in Figures 6 and 7. The device uses a duct section 52 which has a constant diameter and a length of 30 mm. Details describing the embodiments are in the specification and are explained further below. In addition, applicants have attached a Declaration under 37 C.F.R. §1.132 supporting applicants' position that the claimed device is fully enabled.

Neither of the Bellhouse et al. patents cited disclose a device with a claimed duct section component which a "substantially constant cross-sectional area" and as such cannot produce a substantially quasi-steady gas flow that is substantially free of shockwaves in the duct section upstream of the primary shockwave whereby the particles are substantially wholly entrained in the substantially shockwave-free quasi-steady flow for the duration of the time that the particles are in the duct section. Details regarding why the Bellhouse references do not disclose such are provided below. Still further, the attached Declaration under 37 C.F.R. §1.132 explains why the Bellhouse references do not anticipate or render obvious the claimed invention.

Applicants point out that the portion of the Bellhouse component of Figure 1 referred to is the divergent part 37 of a convergent-divergent nozzle. A divergent portion of a convergent-divergent nozzle has a profound effect on the gas flowing through the nozzle. Although a casual observation of

the portion 37 in Figure 1 may make it appear to be a tube of a constant cross-sectional area it does not have a substantially cross-sectional area and as such it cannot provide the desired results. For clarity it is pointed out that it is not applicants contention that the Bellhouse patents do not disclose a device which could produce any quasi-steady flow whatsoever. It is applicants position that particles of the Bellhouse patents are not entrained by the quasi-steady flow "for the duration of time that they are in the duct section" and as such the Bellhouse patents do not meet the claim limitations as described in detail below and in the attached Declaration. The particles in the Bellhouse devices may pass through a very small region of quasi-steady flow after which they go through a shockwave and non-quasi-steady flow before leaving the injection device but not "for the duration of time that they are in the duct section".

REJECTIONS UNDER §112, ¶1

Claim 20 is rejected under 35 U.S.C. §112, first paragraph as failing to comply with the enablement requirement. The Applicants respectfully traverse this rejection.

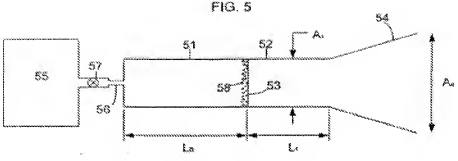
In making this rejection, the Examiner states that the Applicant has not provided sufficient detail as to how the invention is constructed and arranged so as to establish a substantially quasi-steady gas flow that is substantially free of shockwaves in the duct section upstream of the primary shock wave and how/what structure allows for the particles to be substantially wholly entrained in the substantially shockwave-free quasi-steady flow for the duration of time that the particles are in the duct section.

The scope of the required enablement varies inversely with the degree of predictability involved, but even in unpredictable arts, a disclosure of every operable species is not required. A single embodiment may provide broad enablement in cases involving predictable factors, such as mechanical or electrical elements. *In re Vickers*, 141 F.2d 522, 526-27, 61 USPQ 122, 127 (CCPA 1944); *In re Cook*, 439 F.2d 730, 734, 169 USPQ 298, 301 (CCPA 1971).

One of ordinary skill in the art could readily practice the claimed invention without undue experimentation. Performing needle-less injection is a highly predictable art, which can be determined either by calculation or by empirical observation. It is a technique that is widely practiced in the art of fluid dynamics. The Applicants direct the Examiner's attention to embodiments of the present invention that, using the provided description, can be made by one of ordinary skill in the art without undue experiment to achieve the claimed result.

A first embodiment is described on page 11 of the specification and shown in Figure 5, which is reproduced below for the Examiner's convenience.

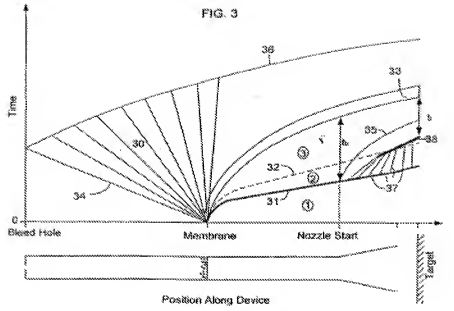
FIG. 5



A driver chamber (51) of constant diameter and having a length of 65mm is provided upstream of a duct section (52), also a constant diameter and having a length of 30mm. The particles (58) are provided adjacent to a membrane (53) that separates the two chambers. A divergent nozzle (54) which expands the area from A_t to A_e is provided downstream of the duct section. As stated in the paragraph bridging pages 11 and 12, the ratio A_t/A_e ranges from 1 to 50. The half angle of the nozzle is preferably 6° (line 3 of page 12). Gas having a pressure of 60 bar (line 11 of page 12) is provided in a reservoir (55) and, in use, is provided to the driver chamber (51) via a bleed hole (56) having a diameter of 0.4mm (line 17 of page 12). Accordingly, an embodiment shown in Figure 5 is fully described with appropriate dimensions allowing the skilled person to readily produce the invention using the provided disclosure. When the valve (57) is opened, high pressure gas is bled from the reservoir (55) into the driver chamber (51). This continues until the pressure in the driver chamber reaches or exceeds the bursting pressure of the membrane (53).

The performance of this specific embodiment after the membrane bursts is illustrated in Figure 3, which is reproduced below. A series of shock waves associated with the "starting process" travel downstream from the membrane position. An expansion wave (34) travels upstream from the membrane position, reaches the far end of the driver chamber and is reflected as expansion wave (36). Due to their mass and inertia, the particles (58) do not travel with the starting process but are accelerated by the gas so as to travel behind the starting process. The length of the chambers (51, 52) is such that the particles are not "overtaken" by the reflected expansion wave 36. Accordingly, as taught in the specification, the particles exit the device after the starting process has exited the device but before the expansion wave (36) exits the device. Accordingly, the particles are entrained in the quasi-steady flow.

FIG. 3



In addition to the embodiment of Figure 5 described above other embodiments are also described (for example, see the gas flow diagram in Figures 6 and 7) and these further assist in teaching a skilled person the range of parameters within which he or she may work the present invention.

Moreover, in view of the predictable nature of the art, it is within the capabilities of a skilled person to modify the length of the driver section or duct section or modify the geometry of the device without undue experimentation. This can be done within limits and it can still be ensured that the particles remain free of the starting process and reflected expansion wave such that they are wholly entrained in the substantially shockwave-free quasi-steady flow for the duration of the time that they are in the duct section.

Thus, the specification provides a skilled person with well-described embodiments such that he or she may practice the claimed invention without undue experimentation.

The Applicants draw the Examiner's attention to the attached Declaration of Nigel Bates (not an inventor) and in particular paragraph 14 of that declaration. Nigel Bates, who is skilled in the field of needle-less syringes (see the attached CV for Nigel Bates), confirms:

> *"In my opinion, sufficient details are given to enable one of ordinary skill in the art to fully work the invention within its claimed scope. In particular, there appear to be no important parameters or dimensions that are left unmentioned in the specification but whose value is important in ensuring that the claimed invention is obtained."*

Lastly, the Rejection has not provided any evidence or reasoning that a skilled person would not be able to make and/or use the invention except for his conclusory statement. As such, Applicants respectfully submit that the lack of enablement rejection is unfounded and request that, in the event that the Examiner wishes to maintain the lack of enablement rejection, evidence forming a basis for such objection be presented.

Therefore, in view of the arguments above, Applicants submit that the claimed invention is fully enabled and respectfully request withdrawal of this rejection.

REJECTIONS UNDER §102

Claims 1-7, 9-25, 27-34, 36 and 55 are rejected under 35 U.S.C. §102(b) as being anticipated by the '796 patent (U.S. Patent No. 5,630,796 to Bellhouse et al.).

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union Oil of California*, 814 F.2d 628, 631; 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987).

The rejected claims are directed to a needleless injection device and a method of accelerating a dose of particles in such a device. An element of the rejected claims is a duct section comprising a tube of substantially constant cross-sectional area. The claims specify that the device is constructed and arranged so that a substantially quasi-steady gas flow that is substantially free of shockwaves is established in the duct section upstream of the primary shock wave. In this manner, the dose of particles is substantially wholly entrained for the duration of time that the particles are in the duct section.

No teaching or suggestion of a claimed element; substantially constant cross-section area

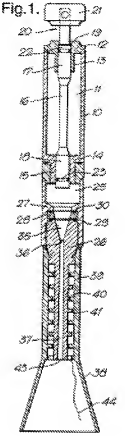
The Rejection asserts that the '796 patent discloses a substantially constant diameter duct section based on the following reasoning:

> (upstream of rupturable membrane 34), substantially constant diameter duct section connected to driver chamber to receive gas therefrom, (constant diameter is within distal section of duct section, fig. 1, wherein the term substantially constant cross-sectional diameter is not fully defined by the specification and therefore since the cross-sectional diameter does not vary significantly the diameter of Bellhouse is seen to be substantially constant), dose of particles P upstream of closure means 34, fig. 8, divergently

Office Action, page 3, lines 1-5.

The Applicants respectfully disagree and submit that the '796 patent does not teach a substantially constant cross-sectional area as claimed by the Applicants. The component referred to by the Examiner is the divergent portion 37 of a convergent-divergent nozzle. FIG. 1 of the '796 patent is reproduced below for the Examiner's convenience.

Fig.1.



As is known by those skilled in the art of fluid dynamics, the divergent portion of a convergent-divergent nozzle has a profound effect on the gas flowing through it. The geometry of the divergent portion 37 is fully explained at line 66 of col. 14-line 4 of col. 15 of the '796 patent. The diameter ranges from 1.5mm at the throat to 2.23mm at the exit of the divergent portion 37. This corresponds to an area increase of from $1.77mm^2$ to $3.9mm^2$. As such, the divergent section has an "area ratio" of 2.21mm. This means that the area at the exit is 2.21 times the area at the throat. As explained in Section 8 of Nigel Bates' Declaration, an area ratio profoundly affects the flow through the divergent portion. As provided in the graph included in Section 8 of Nigel Bates' Declaration, an area ratio of 2.21mm corresponds to a Mach number of 2.54 (provided enough energy is supplied). However, the device of the '796 patent is not correctly expanded so that shockwaves form in the nozzle section.

Bearing in mind the fluid dynamic considerations, the statement made in the Rejection that the diameter of the divergent portion 37 of the '796 patent does not vary significantly is simply not correct. The variation is very significant because it results in the Mach number increasing from 1 (which it would be if the passage was entirely constant in cross-sectional area) to 2.54.

A skilled person in fluid dynamics would interpret "substantially constant" in the rejected claims as meaning only small or minor variations from truly constant such that the Mach number is not increased to the level disclosed in the '796 patent (i.e.,2.54).

Furthermore, the specification evidences that the claimed invention is distinguished from the '796 patent. Figure 1 of the present application is obtained by direct experimentation on the nozzle of the '796 patent and is explained in the specification from line 25 of page 2 to line 2 of page 4. FIG. 1 shows that shockwaves form in the nozzle section and that the particles pass through these shockwaves as they travel through the device. This results, in part, from the fact that the device of the '796 patent has a convergent-divergent nozzle that is not properly expanded.

The solution proposed by the Applicants is to use a substantially constant cross-sectional area duct section that is designed to ensure that the particles do not pass through any shockwaves and remain in the quasi-steady flow.

In light of the above explanation, it is the Applicants' position that the statement in the Rejection that the diameter of the divergent portion 37 of the '796 patent does not vary significantly is incorrect. The Applicants respectfully submit that the claimed "substantially constant" cross-sectional area does not encompass an area ratio of 2.21 as disclosed in the '796 patent. As such, the '796 patent does *not* teach the claimed duct section comprising a tube of substantially constant cross-sectional area.

Rejection Based on Inherency

The Rejection asserts that some limitations in the rejected claims are inherent (see Office Action, page 3, last paragraph). In particular, the Rejection asserts that establishing a substantially quasi-steady flow upstream of the primary shock wave of Claim 20 and entraining and accelerating particles in quasi-steady flow of Claim 20 "are considered inherent functions resulting from the generation of shock waves

by rupturing a membrane at the downstream end of a driver chamber with a constant diameter duct section and divergent nozzle."

These claimed features of the present invention prevent the particles from passing through any shockwave and allow the particles to be carried from their resting point to outside of the device by clean quasi-steady flow. These features are not present in the '796 patent because:

1) the structure disclosed in the '796 patent is distinguished from the claimed invention in that there is no "substantially constant cross-sectional area" and;
2) in the '796 patent, all of the particles pass though a shockwave at some point or another.

When the membrane in the '796 patent bursts, there will be a very small localized area of quasi-steady flow, but, due to the over-expanded nozzle, this will be quickly terminated by a shockwave. The '796 patent therefore does not possess the claimed features.

The Examiner has based the finding of inherency on the "fact" that these flow conditions will occur when a membrane is ruptured at the downstream end of a driver chamber with a constant diameter duct section. However, this is not necessarily the case as it depends upon the whole design of the needle-less syringe to achieve the claimed result. As also discussed above, the '796 patent does not disclose bursting a membrane upstream of a constant diameter duct section.

The Examiner requests evidence that the prior art device does not inherently possess the claimed characteristics. The Applicants submit two items of evidence.

The first evidence is in the present specification itself. Experiments have already been conducted with the device of the '796 patent and the device of the present invention and the results of those experiments are shown in Figures 1 and 3 of the present application. As shown in Figure 1, it has been conclusively proved that the particles in the device of the '796 patent will pass through one or more shockwaves as they leave the device and will not be entrained by quasi-steady flow for the duration of time that they are in the duct section. Figure 3 conclusively proves that the particles in the present invention do not pass through any shockwaves and are entrained in quasi-steady flow for the duration of time that the particles are in the duct section.

Secondly, the attached Declaration of Nigel Bates confirms that the device of the '796 patent behaves as shown in Figure 1 and the device of the present invention behaves as shown in Figure 3. The Applicants urge the Examiner to carefully consider the evidence contained in the present application and the Declaration by a person skilled in the art.

Examiner's Response to Applicants' Previous Arguments

The Rejection argues that "The prior art of record meets the structural limitations of the claim" (see Office Action, sentence bridging pages 4 and 5). As exhaustively discussed above, the '796 patent does not meet the structural limitation of the rejected claims because it does not teach a substantially constant cross-sectional area duct section.

The Rejection also refers to the Applicants' previous admission that the '796 patent creates a quasi-steady flow. As mentioned in Section 13 of Nigel Bates' Declaration, this quasi-steady flow exists only for a very limited spacial region near the bursting point of the membrane and is soon terminated by a shockwave. It is not the Applicants' contention that the '796 patent does not disclose quasi-steady flow. Rather, the Applicants contend that the particles of the '796 patent are not entrained by the quasi-steady flow for the duration of time that they are in the duct section. They pass through a very small region of quasi-steady flow, and then through a shockwave and non-quasi-steady flow before leaving the device.

The Rejection argues that it is not clear as to how the claimed device manages to provide particles entrained in the quasi-steady flow for the duration of time that they are in the duct section. The Applicants note that these features are provided in the specification in detail. One of the design features contributing to this is the substantially constant cross-sectional area duct section. The '796 patent does not teach such a duct section. Accordingly, the claimed invention is novel.

In sum, the substantially constant cross-sectional area duct section allows the starting process (which contains all the shockwaves, etc.) to flow out of the needle-less syringe device faster than the particles. There are no shock-creating features on the inside of the passage that the starting process must pass through. Accordingly, the starting process is able to be swept out of the device by the quasi-steady flow which entrains the particles. This cannot happen in the '796 patent because of the convergent-divergent nozzle design.

In light of the above analysis, the '796 patent does not teach each and every claimed element. Thus, the Applicants contend that the '796 patent does not anticipate the rejected claims and respectfully request that the 35 U.S.C. § 102(e) rejection of Claims 1-7, 9-25, 27-34, 36 and 55 be withdrawn.

REJECTIONS UNDER §103(A)

Claim 37 is rejected under 35 U.S.C. §103(a) as being unpatentable over the '880 patent (U.S. Patent No. 5,899,880 to Bellhouse) in view of the '478 patent (U.S. Patent No. 6,010,478 to Bellhouse).

In order to meet its burden in establishing a rejection under 35 U.S.C. § 103 the Office must first demonstrate that the combined prior art references teach or suggest all the claimed limitations. *See Pharmastem Therapeutics v. Viacell et al.*, 2007 U.S. App. LEXIS 16245 (Fed. Cir. 2007) ("the burden falls on the patent challenger to show by clear and convincing evidence that a person of ordinary skill in the art would have had reason to attempt to make [every element of] the composition or device, or carry out the [entire] claimed process, and would have had a reasonable expectation of success in doing so," (*citing KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1740 (2007); *and see Omegaflex, Inc. v. Parker-Hannifin Corp.*, 2007 U.S. App. LEXIS 14308 (Fed. Cir. 2007) ("[t]he Supreme Court recently explained that 'a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art,' (*citing KSR Int'l Co.* at 1741); *and see Dystar Textilfarben GmbH v. C.H. Patrick Co.*, 464 F.3d 1356, 1360 (Fed. Cir. 2006) ("[once] all claim limitations are found in a number of prior art references, the factfinder must determine '[w]hat the prior art teaches, whether it teaches away from the claimed invention, and whether it motivates a combination of teachings from different references,' (*citing In re Fulton*, 391 F.3d 1195, 1199-1200 (Fed. Cir. 2004))).

To the extent that the Rejection relies upon the '880 patent, the device disclosed therein is substantially the same as the device disclosed in the '796 patent. Accordingly, the Applicants refer the Examiner to the above wherein it is described that the '796 patent is deficient in that it fails to teach at least the claimed element of a duct section comprising a tube of substantially constant cross-sectional area.

The '880 patent fails not only to teach, but also to suggest, this element because the '880 patent is silent on whether its duct section could be modified to have a substantially constant cross-sectional area so as to result in the claimed particle flow. Furthermore, nowhere in the '880 patent is it suggested to modify the device so as to ensure that the particles are entrained only in clean quasi-steady flow.

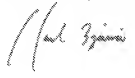
As the '478 patent was cited solely for their alleged teaching of scoring a rupturable membrane in order to limit shedding fragments, it fails to remedy the deficiencies in the '880 patent. Consequently, Claim 37 is not obvious over the cited references, and this rejection may be withdrawn.

CONCLUSION

Applicant submits that all of the claims are in condition for allowance, which action is requested. If the Examiner finds that a telephone conference would expedite the prosecution of this application, please telephone the undersigned at the number provided.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-0815, order number KEMP-002.

Respectfully submitted,
BOZICEVIC, FIELD & FRANCIS LLP



Date: 30 April 2008 By: _____
Karl Bozicevic
Registration No. 28,807

Enclosures:

- Declaration by Nigel Bates under 37 C.F.R. § 1.132; and
- *Curriculum Vitae* of Nigel Bates.

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